DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 17, 2014

Transonic Systems, Inc.
Naveen Thuramalla
VP, Engineering and Clinical Studies
34 Dutch Mill Rd
Ithaca, New York 14850

Re: K134035
Trade/Device Name: Transonic HCM 103 System
Regulation Number: 21 CFR 870.1435
Regulation Name: Single-Function, Preprogrammed Diagnostic Computer
Regulatory Class: Class II
Product Code: DXG
Dated: June 18, 2013
Received: June 19, 2014

Dear Naveen Thuramalla,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

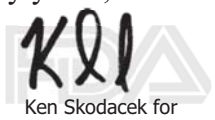
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Ken Skodacek for
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

transonic
THE MEASURE OF BETTER RESULTS.

Transonic Systems Inc.
34 Dutch Mill Rd., Ithaca, NY 14850
p: 800.353.3569 f: 607.257.7256

Indications for Use

510(k) Number (if known): New Submission

Device Name: Transonic HCM103 System

Indications for Use: (Prescription Device)

The Transonic HCM103 system is intended for diagnostic assessment of cardiovascular status and circulatory variables in patients aged 1 month and older. The measurements include continuous cardiac output and associated hemodynamic parameters (such as stroke volume variation; pulse pressure variation, systemic vascular resistance and related index parameters) by continuous arterial pressure waveform analysis. In this stand-alone system, cardiac output (CO) value is entered from such devices as COstatus (HCM101) system or equivalent to calibrate the pressure wave form for measurement of continuous cardiac output. In addition the system also provides heart rate, systolic, diastolic pressures, mean arterial pressure and indexed parameters.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Transonic Systems Inc.
34 Dutch Mill Rd., Ithaca, NY 14850
p: 800.353.3569 f: 607.257.7256

510(k) SUMMARY

Summary of Safety & Effectiveness

Submitter's Name & Address: Transonic Systems Inc.
34 Dutch Mill Road,
Ithaca, NY 14850

Contact Person & Telephone: Naveen Thuramalla
607-257-5300 (*326)

Date Summary Prepared: Dec 16, 2013 (Revised June 18, 2014)

Device Name: Classification Name: Computer, Diagnostic, Pre-programmed, Single-function, 21 CFR 870.1435.
Product Class and Code: DXG and Class II
Classification Panel: Cardiovascular
Common/Usual Name: Extracorporeal, Diagnostic monitor
Proprietary Name: Transonic HCM103 System

Predicate Devices: K082308: MODIFICATION TO VIGILEO ARTERIAL PRESSURE CARDIAC OUTPUT/OXIMETRY MONITOR; EDWARDS LIFESCIENCES, LLC

K010049: PULSECO HEMODYNAMIC MONITOR CM71, LiDCO Ltd. [K023960: LIDCOPLUS HEMODYNAMIC MONITOR SYSTEM is also similar].

Device Description:

In accordance with section 510(k) for the Federal Food, Drug, and Cosmetic Act, Transonic Systems Inc. intends to introduce into interstate commerce the Transonic HCM103 system, which is an apparatus based on arterial pressure waveform analysis to provide diagnostic assessment of cardiovascular status including continuous cardiac output and associated hemodynamic parameters (such as stroke volume variation; pulse pressure variation). In this stand-alone system, calibration value is entered from

such devices as COstatus (HCM101) system or equivalent. In addition the system also measures heart rate, systolic, and diastolic pressures and derives mean arterial pressure. These patients could be in the intensive care units (ICU), operating room (OR) or other such environments.

Components:

Transonic HCM103 system consists of the following components:

Model/Part #	Description
HCM103	Monitor
HCPR	Sensor cable with connector to mate with standard hospital pressure transducer.
HCS40XX	MX950 TranStar Disposable Transducer (K061573) or equivalent.
HCED03	Data Transfer Module

Indication for Use (Prescription Device):

The Transonic HCM103 system is intended for diagnostic assessment of cardiovascular status and circulatory variables in neonatal, pediatric and adult patients. The measurements include continuous cardiac output and associated hemodynamic parameters (such as stroke volume variation; pulse pressure variation, systemic vascular resistance and related index parameters) by continuous arterial pressure waveform analysis. In this stand-alone system, cardiac output (CO) value is entered from such devices as COstatus (HCM101) system or equivalent to calibrate the pressure wave form for measurement of continuous cardiac output. In addition the system also provides heart rate, systolic, diastolic pressures, mean arterial pressure and indexed parameters.

Substantial Equivalence:

The Transonic HCM103 System for use with patients to provide diagnostic assessment of cardiovascular status including continuous cardiac output and associated hemodynamic parameters (such as stroke volume variation; pulse pressure variation, etc) is similar to the VIGILEO arterial pressure cardiac output (K082308) and PULSECO hemodynamic monitor (K010049) which are used to measure continuous cardiac output and related parameters using arterial pressure waveforms.

Substantial equivalence determination is based on the following information and was not based on the assessment of non-clinical performance data.

Proposed device and predicate devices analyze the arterial pressure waveform using pre-existing arterial access in patients to continuously measure cardiac output and other related hemodynamic parameters. PulseCO software which is used with LiDCOplus hemodynamic monitor requires calibration with cardiac output measurement. HCM103 also works in the same manner. For HCM103, cardiac output measurement to calibrate the pressure waveform, which is used to measure continuous cardiac output, is entered from such systems as COstatus (HCM101).

The difference between Vigileo system and the proposed HCM103 system is that the Vigileo system requires use of FloTrac sensor, which is connected to the patient's bedside arterial pressure cable. Transonic HCM103 system requires use of any standard FDA cleared pressure transducer with suitable mating end to be placed in line with the patient's bedside arterial pressure transducer. Vigileo system in conjunction with FloTrac sensor does not require calibration whereas HCM103 system allows for calibration of pressure waveform.

The difference between PulseCO (LiDCO) monitor and the proposed HCM103 system is that the PulseCO monitor connects to the bedside blood pressure monitor whereas the HCM103 system connects to the pre-existing patient's arterial pressure transducer using any standard FDA cleared pressure transducer with mating ends.

These differences do not raise any new issues of safety or effectiveness regarding the use of Transonic HCM103 System.

Performance Testing:

Bench studies confirmed the accuracy of the HCM103 system based on arterial pressure waveform analysis to accurately measure continuous cardiac output, stroke volume variation, pulse pressure variation, systemic vascular resistance index and other related parameters.

Testing consisted of software testing and electrical safety testing according to IEC 60601-1. Prior to shipment, the finished product will be tested and must meet all required release specifications before distribution. The array of testing required for release includes, but are not limited to; physical testing and visual examination (in-process and finished product). The physical testing is defined by Quality Control Test Procedure documents. These tests are established testing procedures that ensure the product's performance parameters conform to the product design specifications. The testing instruction records for each of the individually required procedures are approved, released, distributed, and revised in accordance with document control cGMP's.

Animal and clinical testing was not required to support substantial equivalence.

Safety and Effectiveness:

The successful testing demonstrates the safety and effectiveness of the HCM103 when used for the defined indications for use